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12 *C. R. Bard, Inc. and*
12 *Bard Peripheral Vascular, Inc.*

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA**

17 IN RE: Bard IVC Filters Products Liability Litigation MDL NO. 15-02641-PHX-DGC

18 | This Document Relates to:

19 EMILY LANDRESS,

20 Plaintiff,

CASE NO. CV-15-1884-PHX-DGC

21 || v.

22 C. R. BARD, INC., a New Jersey
23 Corporation; and BARD PERIPHERAL
24 VASCULAR INC., an Arizona
Corporation,

**DEFENDANTS C. R. BARD, INC. AND
BARD PERIPHERAL VASCULAR,
INC.'S ANSWER AND DEFENSES TO
PLAINTIFF'S COMPLAINT AND
DEMAND FOR TRIAL BY JURY**

Defendants.

26 Defendants C. R. Bard, Inc. (“Bard”) and Bard Peripheral Vascular, Inc. (“BPV”)
27 (collectively “Defendants”), through undersigned counsel, hereby file their answer and
28 defenses to Plaintiff’s Complaint (the “Complaint”) as follows:

PARTIES

1. To the extent the allegations in Paragraph 1 of the Plaintiff's Complaint purport to cast liability upon Defendants, either directly or indirectly, those allegations are denied. Defendants are without information sufficient to form a belief as to the truth of the remaining allegations contained in Paragraph 1 of the Plaintiff's Complaint and, on that basis, deny them.

2. Defendants admit that Bard is a New Jersey Corporation and that Bard is authorized to do business, and does business, in the State of Georgia. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters under the trademark G2® Filter System. Bard denies any remaining allegations contained in Paragraph 2 of the Complaint.

3. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the State of Georgia. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademark G2® Filter System. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations contained in Paragraph 3 of the Complaint.

4. The allegations contained in Paragraph 4 of the Complaint are not directed at Bard or BPV, and, as a result, no response is required of these Defendants. To the extent Paragraph 4 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

JURISDICTION AND VENUE

5. Defendants do not contest that the injuries and damages alleged within Plaintiff's Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiff for any amount whatsoever and deny that Plaintiff has suffered any damages whatsoever. Defendants do not dispute that, based on the facts as alleged by

1 Plaintiff, which have not been and could not have been confirmed by Defendants, jurisdiction
2 appears to be proper in the United States District Court for the Northern District of Georgia.

3 6. Defendants do not dispute that, based on the facts as alleged by Plaintiff, which
4 have not been and could not have been confirmed by Defendants, venue appears to be proper
5 in the United States District Court for the Northern District of Georgia.

FACTUAL ALLEGATIONS

7 7. Defendants are without knowledge or information sufficient to form a belief as
8 to the truth of the allegations regarding the trade name of any inferior vena cava filter
9 implanted in Plaintiff and, on that basis, deny them. Defendants further admit that the G2®
10 Express Filter is similar to the G2® Filter, but includes a snare on the sheath of the filter to
11 enhance retrievability. Defendants deny the remaining allegations contained in Paragraph 7 of
12 the Complaint, including those contained in Footnote 1.

13 8. Defendants admit that Bard owns a facility where vena cava filters are
14 manufactured and that filters under the trademark G2® Filter System were manufactured at
15 that facility. Defendants further admit that BPV designs, sells, markets, and distributes
16 inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under
17 the trademark G2®Filter System. Defendants further admit that inferior vena cava filters are
18 intended to prevent injury or death resulting from venous thrombosis and pulmonary
19 embolism. Defendants deny any remaining allegations contained in Paragraph 8 of the
20 Complaint.

21 9. Defendants deny the allegations contained in Paragraph 9 of the Complaint,
22 including all sub-parts thereof.

23 10. Defendants lack knowledge or information sufficient to form a belief as to the
24 truth of the allegation regarding the time frame when inferior vena cava filters were first
25 introduced on the market or the identity of manufacturers of inferior vena cava filters.
26 Defendants deny any remaining allegations of Paragraph 10 of the Complaint.

1 11. Defendants admit that inferior vena cava filters are intended to prevent injury or
2 death resulting from venous thrombosis and pulmonary embolism. Defendants further admit
3 that inferior vena cava filters may be designed for permanent placement, temporary
4 placement, or both. Defendants deny any remaining allegations of Paragraph 11 of the
5 Complaint.

6 12. Defendants admit that the inferior vena cava is a large vein that receives blood
7 from the lower regions of the body and delivers it to the right atrium of the heart. Defendants
8 further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to
9 human health, including sometimes death. Defendants deny any remaining allegations of
10 Paragraph 12 of the Complaint.

11 13. Defendants admit that certain people are at an increased risk for the
12 development of deep vein thrombosis and pulmonary embolus, but lack sufficient information
13 to form a belief as to the truth of the allegations as stated regarding the various risk factors
14 which may predispose an individual to deep vein thrombosis or pulmonary emboli and thus
15 deny them. Defendants deny any remaining allegations of Paragraph 13 of the Complaint.

16 14. Defendants admit that patients at a high risk for developing deep vein
17 thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy,
18 including but not limited to the medications listed in Paragraph 14 of the Complaint.
19 Defendants further admit that inferior vena cava filters may also be used to treat patients who
20 are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants
21 lack knowledge or information sufficient to form a belief as to the truth of any remaining
22 allegations contained in Paragraph 14 of the Complaint and, on that basis, deny them.

23 15. Defendants lack knowledge or information or information sufficient to form a
24 belief as to the truth of the allegation regarding the time frame when inferior vena cava filters
25 were first introduced on the market. Defendants also lack knowledge or information
26 sufficient to form a belief as to the truth of the allegation regarding the time frame when
27 optional or retrievable filters came to be marketed or the other allegations regarding optional

1 or retrievable filters marketed by other manufacturers. Defendants admit that the Recovery®
2 and G2® Filters were cleared by the FDA for optional use as retrievable inferior vena cava
3 filters. Defendants deny any remaining allegations contained in Paragraph 15 of the
4 Complaint.

5 16. Defendants admit that the Recovery® Filter was cleared by the FDA for
6 permanent placement on November 27, 2002, pursuant to an application submitted under
7 Section 510(k) of the Food, Drug and Cosmetic Act of 2005. The allegations pertaining to
8 the requirements of Section 510(k) are legal conclusions of law to which no answer is
9 required. Defendants deny any remaining allegations contained in Paragraph 16 of the
10 Complaint, including any allegations contained in Footnote 2.

11 17. Defendants admit that the Recovery® Filter was cleared by the FDA for
12 retrievable placement on July 25, 2003, pursuant to an application submitted under
13 Section 510(k) of the Food, Drug and Cosmetic Act of 2005. Defendants deny any remaining
14 allegations contained in Paragraph 17 of the Complaint.

15 18. Defendants deny the allegations contained in Paragraph 18 of the Complaint as
16 stated.

17 19. Defendants deny the allegations contained in Paragraph 19 of the Complaint.

18 20. Defendants admit that the Recovery® Filter consists of twelve, shape-memory
19 Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the
20 twelve wires form two levels of filtration for emboli: the legs provide the lower level of
21 filtration, and the arms provide the upper level of filtration. Defendants deny any remaining
22 allegations contained in Paragraph 20 of the Complaint.

23 21. Defendants admit that a nickel-titanium alloy named Nitinol is used in the
24 manufacture of the Recovery Filter and further admit that Nitinol contains shape memory.
25 However, to the extent Paragraph 21 purports to cast liability either directly or indirectly
26 upon Defendants, said Paragraph is expressly denied.

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1 22. Defendants admit that the Recovery® Filter was designed to be inserted
2 endovascularly. Defendants further admit that the Recovery® Filter is designed to be
3 delivered via an introducer sheath, which is included in the delivery system for the device.
4 Defendants deny any remaining allegations of Paragraph 22 of the Complaint.

5 23. Defendants deny the allegations contained in Paragraph 23 of the Complaint.

6 24. Defendants deny the allegations contained in Paragraph 24 of the Complaint.

7 25. Defendants deny the allegations contained in Paragraph 25 of the Complaint.

8 26. Defendants deny the allegations contained in Paragraph 26 of the Complaint.

9 27. Defendants deny the allegations contained in Paragraph 27 of the Complaint.

10 28. Defendants deny the allegations contained in Paragraph 28 of the Complaint.

11 29. Defendants deny the allegations contained in Paragraph 29 of the Complaint.

12 30. Defendants admit that there are various well-documented complications that
13 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
14 Defendants further admit that it is well documented that many instances of filter fracture
15 and/or migration result in no complications whatsoever but, rather, are completely
16 asymptomatic. By way of further response, Defendants state that there are incidents related
17 to the occurrence of known complications associated with every manufacturer of inferior
18 vena cava filters. Defendants deny the remaining allegations of Paragraph 30 of the
19 Complaint, including all sub-parts thereof.

20 31. Defendants deny the allegations contained in Paragraph 31 of the Complaint as
21 stated.

22 32. Defendants deny the allegations contained in Paragraph 32 of the Complaint.

23 33. Defendants deny the allegations contained in Paragraph 33 of the Complaint as
24 stated.

25 34. Defendants deny the allegations contained in Paragraph 34 of the Complaint as
26 stated.

1 35. Defendants admit that, as part of their continuing efforts to constantly evaluate
2 the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are
3 continually striving to improve the life-saving performance of those devices. The G2® Filter
4 was developed in furtherance of those efforts. Defendants deny the remaining allegations
5 contained in Paragraph 35 of the Complaint.

6 36. Defendants deny the allegations contained in Paragraph 36 of the Complaint as
7 stated.

8 37. Defendants admit that certain marketing materials for the G2® Filter contained
9 the words “enhanced fracture resistance,” “improved centering,” and “increased migration
10 resistance.” Defendants deny the remaining allegations contained in Paragraph 37 of the
11 Complaint.

12 38. Defendants deny the allegations contained in Paragraph 38 of the Complaint

13 39. Defendants deny the allegations contained in Paragraph 39 of the Complaint.

14 40. Defendants admit that there are various well-documented complications that
15 may occur as a result of the fracture and/or migration of any inferior vena cava filter.
16 Defendants further admit that it is well documented that many instances of filter fracture
17 and/or migration result in no complications whatsoever but, rather, are completely
18 asymptomatic. By way of further response, Defendants state that there are incidents related
19 to the occurrence of known complications associated with every manufacturer of inferior
20 vena cava filters. Defendants deny the remaining allegations of Paragraph 40 of the
21 Complaint, including all sub-parts thereof.

22 41. Defendants admit that there are various well-documented complications that
23 may occur as the result of the fracture and/or migration of any inferior vena cava filter.
24 Defendants state that there are incidents related to the occurrence of known complications
25 associated with every manufacturer of inferior vena cava filters. By way of further response,
26 Defendants state that information available in the public domain, including the FDA MAUDE

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1 database, is not a comprehensive analysis of all instances of such complications. Defendants
2 deny the remaining allegations of Paragraph 41 of the Complaint.

3 42. Defendants admit that there are various well-documented complications that
4 may occur as the result of the fracture and/or migration of any inferior vena cava filter.
5 Defendants state that there are incidents related to the occurrence of known complications
6 associated with every manufacturer of inferior vena cava filters. By way of further response,
7 Defendants state that information available in the public domain, including the FDA MAUDE
8 database, is not a comprehensive analysis of all instances of such complications. Defendants
9 deny the remaining allegations of Paragraph 42 of the Complaint.

10 43. Defendants deny the allegations contained in Paragraph 43 of the Complaint.

11 44. Defendants deny the allegations contained in Paragraph 44 of the Complaint.

12 45. Defendants deny the allegations contained in Paragraph 45 of the Complaint as
13 stated.

14 46. Defendants deny the allegations contained in Paragraph 46 of the Complaint.

15 47. Defendants deny the allegations contained in Paragraph 47 of the Complaint,
16 including all sub-parts thereof.

17 48. Defendants deny the allegations contained in Paragraph 48 of the Complaint.

18 49. Defendants deny the allegations contained in Paragraph 49 of the Complaint.

19 50. Defendants deny the allegations contained in Paragraph 50 of the Complaint as
20 stated.

21 51. Defendants deny the allegations contained in Paragraph 51 of the Complaint as
22 stated.

23 52. Defendants deny the allegations contained in Paragraph 52 of the Complaint.

24 53. Defendants deny the allegations contained in Paragraph 53 of the Complaint.

25 54. Defendants admit that Bard received a warning letter from the FDA's Los
26 Angeles District Office dated July 13, 2015. Defendants deny the remaining allegations of
27 Paragraph 54 of the Complaint as stated.

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1 55. Defendants deny the allegations contained in Paragraph 55 of the Complaint as
2 stated.

3 56. Defendants deny the allegations contained in Paragraph 56 of the Complaint as
4 stated.

5 57. Defendants deny the allegations contained in Paragraph 57 of the Complaint as
6 stated.

7 58. Defendants deny the allegations contained in Paragraph 58 of the Complaint as
8 stated.

9 59. Defendants are without knowledge or information sufficient to form a belief as
10 to the truth of the allegations contained in Paragraph 59 of the Complaint and, on that basis,
11 deny them.

12 60. Defendants admit that Bard owns a facility where vena cava filters are
13 manufactured and that filters under the trademark G2®X Filter System were manufactured at
14 that facility. Defendants further admit that BPV designs, sells, markets, and distributes
15 inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under
16 the trademark G2®X Filter System. Defendants deny any remaining allegations contained in
17 Paragraph 60 of the Complaint.

18 61. Defendants deny the allegations contained in Paragraph 61 of the Complaint.

19 62. Defendants deny the allegations contained in Paragraph 62 of the Complaint.

20 63. Defendants deny the allegations contained in Paragraph 63 of the Complaint.

21 64. Defendants deny the allegations contained in Paragraph 64 of the Complaint.

22 65. Defendants deny the allegations contained in Paragraph 65 of the Complaint.

23 66. Defendants deny the allegations contained in Paragraph 66 of the Complaint.

24 67. Defendants deny the allegations contained in Paragraph 67 of the Complaint.

25 68. Defendants deny the allegations contained in Paragraph 68 of the Complaint.

26 69. Defendants deny the allegations contained in Paragraph 69 of the Complaint.

27 70. Defendants deny the allegations contained in Paragraph 70 of the Complaint.

71. Defendants deny the allegations contained in Paragraph 71 of the Complaint.

COUNT I – NEGLIGENCE

72. Defendants incorporate by reference their responses to Paragraphs 1-71 of the Complaint as if fully set forth herein.

73. Defendants deny the allegations of Paragraph 73 of the Complaint as stated. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademarks G2® and G2®X Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademarks G2® and G2®X Filter Systems. Defendants deny any remaining allegations contained in Paragraph 73 of the Complaint.

74. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations of Paragraph 74 of the Complaint.

75. The allegations contained in Paragraph 75 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny the remaining allegations contained in Paragraph 75 of the Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of the Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of the Complaint, including all sub-parts thereof.

78. Defendants deny the allegations contained in Paragraph 78 of the Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of the Complaint.

80. Defendants deny the allegations contained in Paragraph 80 of the Complaint, including all sub-parts thereof.

81. Defendants deny the allegations contained in Paragraph 81 of the Complaint.

1 **COUNT II – NEGLIGENT FAILURE TO WARN**

2 82. Defendants incorporate by reference their responses to Paragraphs 1-81 of the
3 Complaint as if fully set forth herein.

4 83. Defendants deny the allegations of Paragraph 83 of the Complaint as stated. By
5 way of further response, Defendants admit that Bard owns a facility where vena cava filters
6 are manufactured and that filters under the trademark G2® Filter Systems were manufactured
7 at that facility. Defendants further admit that BPV designs, sells, markets, and distributes
8 inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under
9 the trademark G2® Filter Systems. Defendants deny any remaining allegations contained in
10 Paragraph 83 of the Complaint.

11 84. Defendants deny the allegations contained in Paragraph 84 of the Complaint.

12 85. Defendants deny the allegations contained in Paragraph 85 of the Complaint.

13 86. The allegations contained in Paragraph 86 regarding Defendants' duty are legal
14 conclusions of law, and no answer is required. To the extent a response is required,
15 Defendants deny the allegations. Defendants deny the remaining allegations contained in
16 Paragraph 86 of the Complaint.

17 87. The allegations contained in Paragraph 87 regarding Defendants' duty are legal
18 conclusions of law, and no answer is required. To the extent a response is required,
19 Defendants deny the allegations. Defendants deny the remaining allegations contained in
20 Paragraph 87 of the Complaint.

21 88. Defendants deny the allegations contained in Paragraph 88 of the Complaint.

22 89. Defendants deny the allegations contained in Paragraph 89 of the Complaint.

23 90. Defendants deny the allegations contained in Paragraph 90 of the Complaint.

24 91. Defendants deny the allegations contained in Paragraph 91 of the Complaint.

25 92. Defendants deny the allegations contained in Paragraph 92 of the Complaint.

26 93. Defendants deny the allegations contained in Paragraph 93 of the Complaint.

27 94. Defendants deny the allegations contained in Paragraph 94 of the Complaint.

1 **COUNT III – STRICT LIABILITY FAILURE TO WARN**

2 95. Defendants incorporate by reference their responses to Paragraphs 1-94 of the
3 Complaint as if fully set forth herein.

4 96. Defendants are without knowledge or information sufficient to form a belief as
5 to the truth of the allegations regarding the trade name of any inferior vena cava filter
6 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
7 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
8 the trademarks G2® and G2®X Filter Systems were manufactured at that facility.
9 Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava
10 filters and that BPV designed, sold, marketed, and distributed filters under the trademarks
11 G2® and G2®X Filter Systems. Defendants deny any remaining allegations contained in
12 Paragraph 96 of the Complaint.

13 97. Defendants deny the allegations contained in Paragraph 97 of the Complaint.

14 98. The allegations contained in Paragraph 98 regarding Defendants' duty are legal
15 conclusions of law, and no answer is required. To the extent a response is required,
16 Defendants deny the allegations. Defendants deny the remaining allegations contained in
17 Paragraph 98 of the Complaint.

18 99. Defendants deny the allegations contained in Paragraph 99 of the Complaint.

19 100. Defendants deny the allegations contained in Paragraph 100 of the Complaint.

20 101. Defendants deny the allegations contained in Paragraph 101 of the Complaint.

21 102. Defendants deny the allegations contained in Paragraph 102 of the Complaint.

22 103. Defendants deny the allegations contained in Paragraph 103 of the Complaint.

23 104. Defendants deny the allegations contained in Paragraph 104 of the Complaint.

24 105. Defendants deny the allegations contained in Paragraph 105 of the Complaint.

25 106. Defendants deny the allegations contained in Paragraph 106 of the Complaint.

1 **COUNT IV – STRICT PRODUCTS LIABILITY DESIGN DEFECTS**

2 107. Defendants incorporate by reference their responses to Paragraphs 1-106 of the
3 Complaint as if fully set forth herein.

4 108. Defendants are without knowledge or information sufficient to form a belief as
5 to the truth of the allegations regarding the trade name of any inferior vena cava filter
6 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
7 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
8 the trademarks G2® and G2®X Filter Systems were manufactured at that facility.
9 Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava
10 filters and that BPV designed, sold, marketed, and distributed filters under the trademarks
11 G2® and G2®X Filter Systems. Defendants deny any remaining allegations contained in
12 Paragraph 108 of the Complaint.

13 109. Defendants deny the allegations contained in Paragraph 109 of the Complaint.

14 110. Defendants deny the allegations contained in Paragraph 110 of the Complaint.

15 111. Defendants deny the allegations contained in Paragraph 111 of the Complaint.

16 112. Defendants deny the allegations contained in Paragraph 112 of the Complaint.

17 113. Defendants deny the allegations contained in Paragraph 113 of the Complaint.

18 114. Defendants deny the allegations contained in Paragraph 114 of the Complaint.

19 115. Defendants deny the allegations contained in Paragraph 115 of the Complaint.

20 **COUNT V – STRICT LIABILITY MANUFACTURING DEFECT**

21 116. Defendants incorporate by reference their responses to Paragraphs 1-115 of the
22 Complaint as if fully set forth herein.

23 117. Defendants are without knowledge or information sufficient to form a belief as
24 to the truth of the allegations regarding the trade name of any inferior vena cava filter
25 implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants
26 admit that Bard owns a facility where vena cava filters are manufactured and that filters under
27 the trademark G2®X Filter System were manufactured at that facility. Defendants further

1 admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV
2 designed, sold, marketed, and distributed filters under the trademarks G2®X Filter System.
3 Defendants deny any remaining allegations contained in Paragraph 117 of the Complaint.

4 118. Defendants deny the allegations contained in Paragraph 118 of the Complaint.

5 119. Defendants deny the allegations contained in Paragraph 119 of the Complaint.

6 120. Defendants deny the allegations contained in Paragraph 120 of the Complaint.

7 121. Defendants deny the allegations contained in Paragraph 121 of the Complaint.

8 **COUNT VI – BREACH OF EXPRESS WARRANTY**

9 122. Defendants incorporate by reference their responses to Paragraphs 1-121 of the
10 Complaint as if fully set forth herein.

11 123. Defendants deny the allegations contained in Paragraph 123 of the Complaint.

12 124. Defendants deny the allegations contained in Paragraph 124 of the Complaint.

13 125. Defendants deny the allegations contained in Paragraph 125 of the Complaint.

14 126. Defendants deny the allegations contained in Paragraph 126 of the Complaint.

15 127. Defendants deny the allegations contained in Paragraph 127 of the Complaint.

16 128. Defendants deny the allegations contained in Paragraph 128 of the Complaint,
17 including all sub-parts thereof.

18 129. Defendants deny the allegations contained in Paragraph 129 of the Complaint.

19 130. Defendants deny the allegations contained in Paragraph 130 of the Complaint.

20 131. Defendants deny the allegations contained in Paragraph 131 of the Complaint.

21 132. Defendants deny the allegations contained in Paragraph 132 of the Complaint.

22 **COUNT VII – BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**

23 133. Defendants incorporate by reference their responses to Paragraphs 1-132 of the
24 Complaint as if fully set forth herein.

25 134. Defendants deny the allegations contained in Paragraph 134 of the Complaint
26 as stated. By way of further response, Defendants admit that Bard owns a facility where vena
27 cava filters are manufactured and that filters under the trademarks G2® and G2®X Filter

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1 Systems were manufactured at that facility. Defendants further admit that BPV designs, sells,
2 markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and
3 distributed filters under the trademarks G2® and G2®X Filter Systems. Defendants deny any
4 remaining allegations contained in Paragraph 134 of the Complaint.

5 135. Defendants deny the allegations contained in Paragraph 135 of the Complaint.

6 136. Defendants deny the allegations contained in Paragraph 136 of the Complaint.

7 137. Defendants deny the allegations contained in Paragraph 137 of the Complaint,
8 including all sub-parts thereof.

9 138. Defendants deny the allegations contained in Paragraph 138 of the Complaint.

10 139. Defendants deny the allegations contained in Paragraph 139 of the Complaint.

11 140. Defendants deny the allegations contained in Paragraph 140 of the Complaint.

12 141. Defendants deny the allegations contained in Paragraph 141 of the Complaint.

13 **COUNT VIII – FRAUDULENT CONCEALMENT**

14 142. Defendants incorporate by reference their responses to Paragraphs 1-141 of the
15 Complaint as if fully set forth herein.

16 143. Defendants deny the allegations contained in Paragraph 143 of the Complaint.

17 144. Defendants deny the allegations contained in Paragraph 144 of the Complaint.

18 145. Defendants deny the allegations contained in Paragraph 145 of the Complaint.

19 146. Defendants deny the allegations contained in Paragraph 146 of the Complaint.

20 147. Defendants deny the allegations contained in Paragraph 147 of the Complaint.

21 148. Defendants deny the allegations contained in Paragraph 148 of the Complaint.

22 149. Defendants deny the allegations contained in Paragraph 149 of the Complaint.

23 150. Defendants deny the allegations contained in Paragraph 150 of the Complaint.

24 151. Defendants deny the allegations contained in Paragraph 151 of the Complaint.

25 152. The allegations contained in Paragraph 152 regarding Defendants' duty are
26 legal conclusions of law, and no answer is required. To the extent a response is required,

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1 Defendants deny the allegations. Defendants deny the remaining allegations contained in
2 Paragraph 152 of the Complaint.

3 153. Defendants deny the allegations contained in Paragraph 153 of the Complaint.

4 **COUNT IX – NEGLIGENT MISREPRESENTATION**

5 154. Defendants incorporate by reference their responses to Paragraphs 1-153 of the
6 Complaint as if fully set forth herein.

7 155. Defendants deny the allegations contained in Paragraph 155 of the Complaint,
8 including all sub-parts thereof.

9 156. Defendants deny the allegations contained in Paragraph 156 of the Complaint.

10 157. Defendants deny the allegations contained in Paragraph 157 of the Complaint.

11 158. Defendants deny the allegations contained in Paragraph 158 of the Complaint.

12 159. Defendants deny the allegations contained in Paragraph 159 of the Complaint.

13 160. Defendants deny the allegations contained in Paragraph 160 of the Complaint.

14 161. Defendants deny the allegations contained in Paragraph 161 of the Complaint.

15 162. Defendants deny the allegations contained in Paragraph 162 of the Complaint.

16 163. Defendants deny the allegations contained in Paragraph 163 of the Complaint.

17 **COUNT X – FRAUDULENT MISREPRESENTATION**

18 164. Defendants incorporate by reference their responses to Paragraphs 1-163 of the
19 Complaint as if fully set forth herein.

20 165. Defendants deny the allegations contained in Paragraph 165 of the Complaint,
21 including all sub-parts thereof.

22 166. Defendants deny the allegations contained in Paragraph 166 of the Complaint.

23 167. Defendants deny the allegations contained in Paragraph 167 of the Complaint.

24 168. Defendants deny the allegations contained in Paragraph 168 of the Complaint.

25 169. Defendants deny the allegations contained in Paragraph 169 of the Complaint.

26 170. Defendants deny the allegations contained in Paragraph 170 of the Complaint.

27 171. Defendants deny the allegations contained in Paragraph 171 of the Complaint.

172. Defendants deny the allegations contained in Paragraph 172 of the Complaint.

173. Defendants deny the allegations contained in Paragraph 173 of the Complaint.

174. Defendants deny the allegations contained in Paragraph 174 of the Complaint.

175. Defendants deny the allegations contained in Paragraph 175 of the Complaint.

176. Defendants deny the allegations contained in Paragraph 176 of the Complaint.

PUNITIVE DAMAGES ALLEGATIONS

177. Defendants incorporate by reference their responses to Paragraphs 1-176 of the Complaint as if fully set forth herein.

178. Defendants deny the allegations contained in Paragraph 178 of the Complaint.

179. Defendants deny the allegations contained in Paragraph 179 of the Complaint, including all sub-parts thereof.

180. Defendants deny the allegations contained in Paragraph 180 of the Complaint.

181. Defendants deny the allegations contained in Paragraph 181 of the Complaint.

PRAYER FOR DAMAGES

Furthermore, responding to the unnumbered Paragraph, including sub-parts, following the heading “PAYER FOR DAMAGES” and beginning “WHEREFORE,” Defendants deny the allegations contained in such Paragraph and all sub-parts thereof.

Further, responding to the prayer for relief as to the first cause of action for negligence against Defendants including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

Further, responding to the prayer for relief as to the second cause of action for negligent failure to warn against Defendants, including sub-parts numbered 1 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that Plaintiff is entitled to any relief under Georgia law.

1 Further, responding to the prayer for relief as to the third cause of action for strict
2 liability – failure to warn against Defendants, including sub-parts numbered 1 through 6,
3 Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny
4 that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that
5 Plaintiff is entitled to any relief under Georgia law.

6 Further, responding to the prayer for relief as to the fourth cause of action for strict
7 liability – design defect against Defendants, including sub-parts numbered 1 through 6,
8 Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny
9 that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that
10 Plaintiff is entitled to any relief under Georgia law.

11 Further, responding to the prayer for relief as to the fifth cause of action for strict
12 liability – manufacturing defect against Defendants, including sub-parts numbered 1 through
13 6, Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants
14 deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants further
15 deny that Plaintiff is entitled to any relief under Georgia law.

16 Further, responding to the prayer for relief as to the sixth cause of action for breach of
17 express warranty against Defendants, including sub-parts numbered 1 through 6, Defendants
18 deny the allegations contained in such Paragraph and sub-parts. Defendants deny that
19 Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that
20 Plaintiff is entitled to any relief under Georgia law.

21 Further, responding to the prayer for relief as to the seventh cause of action for breach
22 of implied warranty of merchantability against Defendants, including sub-parts numbered 1
23 through 6, Defendants deny the allegations contained in such Paragraph and sub-parts.
24 Defendants deny that Plaintiff is entitled to any relief requested in the Complaint. Defendants
25 further deny that Plaintiff is entitled to any relief under Georgia law.

26 Further, responding to the prayer for relief as to the eighth cause of action for
27 fraudulent concealment against Defendants, including sub-parts numbered 1 through 6,
28

1 Defendants deny the allegations contained in such Paragraph and sub-parts. Defendants deny
2 that Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that
3 Plaintiff is entitled to any relief under Georgia law.

4 Further, responding to the prayer for relief as to the ninth cause of action for negligent
5 misrepresentation against Defendants, including sub-parts numbered 1 through 6, Defendants
6 deny the allegations contained in such Paragraph and sub-parts. Defendants deny that
7 Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that
8 Plaintiff is entitled to any relief under Georgia law.

9 Further, responding to the prayer for relief as to the tenth cause of action for fraudulent
10 misrepresentation against Defendants, including sub-parts numbered 1 through 6, Defendants
11 deny the allegations contained in such Paragraph and sub-parts. Defendants deny that
12 Plaintiff is entitled to any relief requested in the Complaint. Defendants further deny that
13 Plaintiff is entitled to any relief under Georgia law.

14 Defendants further deny each and every allegation not specifically admitted herein.

15 Defendants allege as affirmative defenses the following:

16 1. Plaintiff's Complaint filed herein fails to state a claim or claims upon which
17 relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

18 2. The sole proximate cause of Plaintiff's damages, if any were sustained, was the
19 negligence of a person or persons or entity for whose acts or omissions Defendants were and
20 are in no way liable.

21 3. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of
22 limitations and/or statute of repose.

23 4. If Plaintiff has been damaged, which Defendants deny, any recovery by
24 Plaintiff is barred to the extent Plaintiff voluntarily exposed herself to a known risk and/or
25 failed to mitigate their alleged damages. To the extent Plaintiff has failed to mitigate her
26 alleged damages, any recovery shall not include alleged damages that could have been
27 avoided by reasonable care and diligence.

1 5. If Plaintiff has been damaged, which Defendants deny, such damages were
2 caused by the negligence or fault of Plaintiff.

3 6. If Plaintiff has been damaged, which Defendants deny, such damages were
4 caused by the negligence or fault of persons and/or entities for whose conduct Defendants are
5 not legally responsible.

6 7. The conduct of Defendants and the subject product at all times conformed with
7 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent
8 federal statutes and regulations. Accordingly, Plaintiff's claims are barred, in whole or in
9 part, under the doctrine of federal preemption, and granting the relief requested would
10 impermissibly infringe upon and conflict with federal laws, regulations, and policies in
11 violation of the Supremacy Clause of the United States Constitution.

12 8. If Plaintiff has been damaged, which Defendants deny, such damages were
13 caused by unforeseeable, independent, intervening, and/or superseding events for which
14 Defendants are not legally responsible.

15 9. There was no defect in the product at issue with the result that Plaintiff is not
16 entitled to recover against Defendants in this cause.

17 10. If there were any defect in the products – and Defendants deny that there were
18 any defects – nevertheless, there was no causal connection between any alleged defect and
19 the product on the one hand and any damage to Plaintiff on the other with the result that
20 Plaintiff is not entitled to recover against Defendants in this cause.

21 11. Plaintiff's injuries, losses or damages, if any, were caused by or contributed to
22 by other persons or entities that are severally liable for all or part of Plaintiff's alleged
23 injuries, losses or damages. If Defendants are held liable to Plaintiff, which liability is
24 specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification,
25 either in whole or in part, from all persons or entities whose negligence or fault proximately
26 caused or contributed to cause Plaintiff's alleged damages.

1 12. Plaintiff's claims are barred to the extent that the injuries alleged in the
2 Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a
3 manner not intended by Defendants and over which Defendants had no control.

4 13. Plaintiff's claims are barred to the extent that the injuries alleged in the
5 Complaint were caused by a substantial change in the product after leaving the possession,
6 custody, and control of Defendants.

7 14. Plaintiff's breach of warranty claims are barred because: (1) Defendants did not
8 make any warranties, express or implied, to Plaintiff; (2) there was a lack of privity between
9 Defendants and Plaintiff; and (3) notice of an alleged breach was not given to the seller or
10 Defendants.

11 15. Plaintiff's claims for breach of implied warranty must fail because the product
12 was not used for its ordinary purpose.

13 16. Defendants neither had nor breached any alleged duty to warn with respect to
14 the product, with the result that Plaintiff is not entitled to recover in this cause.

15 17. Plaintiff's claims are barred by Defendants' dissemination of legally adequate
16 warnings and instructions to learned intermediaries.

17 18. At all relevant times, herein, Plaintiff's physicians were in the position of
18 sophisticated purchasers, fully knowledgeable and informed with respect to the risks and
19 benefits of the subject product.

20 19. If Plaintiff has been damaged, which Defendants deny, the actions of persons or
21 entities for whose conduct Defendants are not legally responsible and the independent
22 knowledge of these persons or entities of the risks inherent in the use of the product and other
23 independent causes, constitute an intervening and superseding cause of Plaintiff's alleged
24 damages.

25 20. To the extent that injuries and damages sustained by Plaintiff, as alleged in
26 Plaintiff's Complaint, were caused directly, solely, and proximately by sensitivities, medical

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1 conditions, and idiosyncrasies peculiar to Plaintiff not found in the general public, they were
2 unknown, unknowable, or not reasonably foreseeable to Defendants.

3 21. Defendants believe, and upon that ground allege, that Plaintiff were advised of
4 the risks associated with the matters alleged in Plaintiff's Complaint and knowingly and
5 voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed
6 consent, release, waiver, or comparative fault, this conduct bars in whole or in part the
7 damages that Plaintiff seek to recover herein.

8 22. At all relevant times during which the device at issue was designed, developed,
9 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
10 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
11 information, and instructions, all pursuant to generally recognized prevailing industry
12 standards and state-of-the-art in existence at the time.

13 23. Plaintiff's claims are barred because Plaintiff suffered no injury or damages as a
14 result of the alleged conduct and do not have any right, standing, or competency to maintain
15 claims for damages or other relief.

16 24. Plaintiff's claims are barred, in whole or in part, by the doctrines of waiver,
17 estoppel, and/or laches.

18 25. If Plaintiff suffered any damages or injuries, which are denied, Defendants state
19 that Plaintiff's recovery is barred, in whole or in part, or subject to reduction, under the
20 doctrines of contributory and/or comparative negligence.

21 26. In the further alternative, and only in the event that it is determined that
22 Plaintiff is entitled to recover against Defendants, recovery should be reduced in proportion to
23 the degree or percentage of negligence, fault or exposure to products attributable to Plaintiff,
24 any other defendants, third-party defendants, or other persons, including any party immune
25 because bankruptcy renders them immune from further litigation, as well as any party, co-
26 defendant, or non-parties with whom Plaintiff has settled or may settle in the future.

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1 27. Should Defendants be held liable to Plaintiff, which liability is specifically
2 denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiff
3 from all collateral sources.

4 28. Plaintiff's claims may be barred, in whole or in part, from seeking recovery
5 against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of
6 claims, and the prohibition on double recovery for the same injury.

7 29. The injuries and damages allegedly sustained by Plaintiff may be due to the
8 operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiff
9 over which Defendants had no control.

10 30. The conduct of Defendants and all activities with respect to the subject product
11 have been and are under the supervision of the Federal Food and Drug Administration
12 ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief,
13 is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

14 31. Defendants assert any and all defenses, claims, credits, offsets, or remedies
15 provided by the Restatements (Second and Third) of Torts and reserve the right to amend
16 their Answer to file such further pleadings as are necessary to preserve and assert such
17 defenses, claims, credits, offsets, or remedies.

18 32. The device at issue complied with any applicable product safety statute or
19 administrative regulation, and therefore Plaintiff's defective design and warnings-based
20 claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and
21 comments thereto.

22 33. Plaintiff cannot show that any reasonable alternative design would have
23 rendered the G2® Filter inferior vena cava filter device as alleged in Plaintiff's Complaint to
24 be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could
25 Defendants have known of any alternative design that may be identified by Plaintiff.

26 34. The device at issue was not sold in a defective condition unreasonably
27 dangerous to the user or consumer, and therefore Plaintiff's claims are barred under the

1 Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and
 2 comparable provisions of the Restatement (Third) of Torts (Products Liability).

3 35. At all relevant times during which the device at issue was designed, developed,
 4 manufactured, and sold, the device was reasonably safe and reasonably fit for its intended
 5 use, was not defective or unreasonably dangerous, and was accompanied by proper warnings,
 6 information, and instructions, all pursuant to generally recognized prevailing industry
 7 standards and state-of-the-art in existence at the time.

8 36. Defendants specifically plead all affirmative defenses under the Uniform
 9 Commercial Code (“UCC”) now existing or which may arise in the future, including those
 10 defenses provided by UCC §§ 2-607 and 2-709.

11 37. Plaintiff’s alleged damages, if any, should be apportioned among all parties at
 12 fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors
 13 Act.

14 38. No act or omission of Defendants was malicious, willful, wanton, reckless, or
 15 grossly negligent, and, therefore, any award of punitive damages is barred.

16 39. To the extent the claims asserted in Plaintiff’s Complaint are based on a theory
 17 providing for liability without proof of defect and proof of causation, the claims violate
 18 Defendants’ rights under the Constitution of the United States and analogous provisions of
 19 the Georgia Constitution.

20 40. Regarding Plaintiff’s demand for punitive damages, Defendants specifically
 21 incorporate by reference any and all standards of limitations regarding the determination
 22 and/or enforceability of punitive damages awards that arose in the decisions of *BMW of*
No. America v. Gore, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool*
Group, Inc., 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct.
 25 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S.
 26 June 25, 2008) and their progeny as well as other similar cases under both federal and state
 27 law.

1 41. Plaintiff's claims for punitive or exemplary damages violate, and are therefore
2 barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of
3 the United States of America, and similar provisions of the Georgia Constitution, on grounds
4 including the following:

- 5 (a) it is a violation of the Due Process and Equal Protection Clauses of the
6 Fourteenth Amendment of the United States Constitution to impose punitive
7 damages, which are penal in nature, against a civil defendant upon the plaintiff
8 satisfying a burden of proof which is less than the "beyond a reasonable doubt"
9 burden of proof required in criminal cases;
- 10 (b) the procedures pursuant to which punitive damages are awarded may result in
11 the award of joint and several judgments against multiple defendants for
12 different alleged acts of wrongdoing, which infringes upon the Due Process and
13 Equal Protection Clauses of the Fourteenth Amendment of the United States
14 Constitution;
- 15 (c) the procedures to which punitive damages are awarded fail to provide a
16 reasonable limit on the amount of the award against Defendants, which thereby
17 violates the Due Process Clause of the Fourteenth Amendment of the United
18 States Constitution;
- 19 (d) the procedures pursuant to which punitive damages are awarded fail to provide
20 specific standards for the amount of the award of punitive damages which
21 thereby violates the Due Process Clause of the Fourteenth Amendment of the
22 United States Constitution;
- 23 (e) the procedures pursuant to which punitive damages are awarded result in the
24 imposition of different penalties for the same or similar acts, and thus violate
25 the Equal Protection Clause of the Fourteenth Amendment of the United States
26 Constitution;

1 (f) the procedures pursuant to which punitive damages are awarded permit the
2 imposition of punitive damages in excess of the maximum criminal fine for the
3 same or similar conduct, which thereby infringes upon the Due Process Clause
4 of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the
5 Fourteenth Amendment of the United States Constitution;
6 (g) the procedures pursuant to which punitive damages are awarded permit the
7 imposition of excessive fines in violation of the Eighth Amendment of the
8 United States Constitution;
9 (h) the award of punitive damages to the plaintiff in this action would constitute a
10 deprivation of property without due process of law; and
11 (i) the procedures pursuant to which punitive damages are awarded permit the
12 imposition of an excessive fine and penalty.

13 42. Defendants expressly reserve the right to raise as an affirmative defense that
14 Plaintiff has failed to join all parties necessary for a just adjudication of this action, should
15 discovery reveal the existence of facts to support such defense.

16 43. The design complained of in Plaintiffs' Complaint, the alleged defects of the
17 product, and/or any alternative design claimed by Plaintiffs were not known and, in light of
18 the existing, reasonably-available scientific and technological knowledge, could not have
19 been known at the time the product at issue was designed, manufactured, and sold. Any
20 alleged alternative design was not scientifically or technologically feasible or economically
21 practical.

22 44. To the extent the Complaint alleges misrepresentation and fraud, these
23 allegations do not comply with the requisite of particularity under applicable procedural rules
24 and/or law.

25 45. Defendants reserve the right to raise such other affirmative defenses as may be
26 available or apparent during discovery or as may be raised or asserted by other defendants in
27 this case. Defendants have not knowingly or intentionally waived any applicable affirmative
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1 defense. If it appears that any affirmative defense is or may be applicable after Defendants
2 have had the opportunity to conduct reasonable discovery in this matter, Defendants will
3 assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

4 **REQUEST FOR JURY TRIAL**

5 Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury
6 on all issues appropriate for jury determination.

7 **WHEREFORE**, Defendants aver that Plaintiff is not entitled to the relief demanded in
8 the Complaint, and these Defendants, having fully answered, pray that this action against
9 them be dismissed and that they be awarded their costs in defending this action and that they
10 be granted such other and further relief as the Court deems just and appropriate.

11 This 23rd day of October 2015.

12
13 s/Richard B. North, Jr.
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23 **Attorney for Defendants C. R. Bard, Inc. and**
24 **Bard Peripheral Vascular, Inc.**

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1 **CERTIFICATE OF SERVICE**
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3 I HEREBY CERTIFY that on October 23, 2015, I electronically filed the foregoing
4 with the Clerk of the Court by using the CM/ECF system which will send notification of such
5 filing to all counsel of record.

6 s/Richard B. North, Jr.
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